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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,530	01/17/2002	Jeffrey A. Ledbetter	30906/41458UTL2	8993

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/053,530	**Applicant(s)** LEDBETTER ET AL.	
	Examiner David J. Blanchard	**Art Unit** 1643	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *23-44,47,48,102-106 and 142-145*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DAVID J. BLANCHARD
PATENT EXAMINER

Continuation of 3. NOTE: Entry of the amendment filed 12/12/2006 would raise new issue, requiring new considerations, new search and new rejections. As currently presented claim 23 has been amended to delete the proviso that "when the hinge peptide contains two cysteines" as it pertains to the limitation wherein the first cysteine of the hinge that is responsible for forming a disulfide bond with a light chain constant region in a naturally occurring IgG or IgA antibody is not deleted or substituted. Thus, as previously presented the claims recited the limitation that the hinge peptide cysteines were reduced to two and the conditional limitation that when the hinge peptide contains two cysteines then the first cysteine of the hinge that is responsible for forming a disulfide bond with a light chain constant region of IgG or IgA was not deleted or substuituted, however, as presently amended the claims now require two hinge cysteines in which the first cysteine of the hinge that is responsible for forming a disulfide bond with a light chain constant regionin a naturally occurring IgG or IgA antibody is not deleted or substituted, which implicitly requries the deletion of one of the other two hinge cysteines of IgG1, for example. It is noted that in IgG2, IgG3 and IgG4 it is the CH1 cysteine residue(s) that is/are responsible for disulfide bond formation with the light chain. Thus, as presently amended the claims now recite limitations that were not previously presented and require further consideration and search. Further, the current amendment to claim 23 introduces new matter into the claims. As it pertains to single polypeptide chain binding molecules, the as flled disclosure does not provide adequate written support for the particular limitations currently claimed. For example, at pg. 29 "The Cys residue of the hinge which makes a disulfide bond with a corresponding Cys of the light chain, to hold the heavy and light chains of the native antibody molecule, can be deleted or, preferably is substituted with, e.g., a Pro residue or the like." Further, there is no clear contemplation in the as filed disclsoure of deleting one of the other two cysteines in the hinge region of IgG1, i.e., deletion of one proline in the IgG1 hinge sequence CPPC, as presently required by the claims. Additionally, the amendment to claim 24 introduces new matter. The response points to pg. 12, lines 10-12, which discloses that the CH2 and CH3 constant regions are from a human immunoglobulin heavy chain, which does not provide adequate written support for the limitation of an IgG CH3 domain in combination with just any heavy chain CH2, particularly where lines 13-15 on the same pg. disclose that the CH2 and CH3 are of an isotype selected from human IgG and human IgA. The as filed disclsoure as pointed to by applicant does not provide adequate written supprt for the use of just any CH2 region in combination with an IgG CH3 region, partiuclarly where the CH2 and CH3 are different isotypes as presently amended.
The issue of new matter as discussed supra might be remedied if Applicant were to point to padicular disclosures in the specification, including the claims, as originally filed, that are believed to provide proper written support for the current claim language.

Additionally, it is noted that the amendments to claim 24 would not overcome the art of Gillies et al of record, if entered.

Respectfully,
David J. Blanchard
571-272-0827